DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel

Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

February 23, 2005

Via Federal Express
Departmental Appeals Board
Room 637-D
Hubert H. Humphrey Bldg.
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: In re Korangy Radiology Associates, P.A., et al.
Board Docket No: A-05-35

Dear Sir or Madam:

Enclosed for filing in the above-captioned matter is the original and two copies of Complainant's Brief in Opposition to Respondents' Appeal and Request for Oral Argument. If you have any questions, please call me at (301) 827-5523. Thank you.

Sincerely,

Jennifer E. Dayok
Associate Chief Counsel
for Enforcement

Enclosure

cc w/encl.:
Dockets Management Branch (HFA-305)
Henry E. Schwartz, Esq.

2003H-0432

BRF 3

UNITED STATES OF AMERICA
BEFORE THE DEPARTMENTAL APPEALS BOARD
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of KORANGY RADIOLOGY ASSOCIATES, P.A., trading as BALTIMORE IMAGING CENTERS, a corporation, and, AMILE A. KORANGY, M.D., an individual.	)	Board Docket No.: A-05-35 FDA Docket No.: 2003H-0432

COMPLAINANT'S BRIEF IN OPPOSITION TO RESPONDENTS' APPEAL AND REQUEST FOR ORAL ARGUMENT

INTRODUCTION

On September 22, 2003, Complainant, the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA), filed a Complaint seeking civil money penalties (CMP) under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b, against Respondents Korangy Radiology Associates, P.A. (KRA), a mammography facility doing business as Baltimore Imaging Centers (BIC), and Amile A. Korangy, M.D., the President and owner of KRA and the Lead Interpreting Physician and Supervision Radiologist of BIC. The Complaint alleged that between May 7, 2002, and July 25, 2002, BIC failed to obtain the certificate required by the MQSA to perform mammography examinations and conducted 192 mammography examinations while uncertified.

On May 27, 2004, the Presiding Officer granted Complainant's Motion for Partial Summary Decision, finding that Respondents were each liable for 193 violations of the

MQSA--one for failing to obtain a certificate, and 192 for each of the mammography examinations performed while the facility was uncertified.

On September 20, 2004, the Presiding Officer held an oral hearing with respect to the amount of the penalty to be imposed, including any mitigating or aggravating factors applicable under 21 C.F.R. § 17.34. The parties filed simultaneous post-hearing briefs on the penalty amount on December 3, 2004. On December 17, 2004, the Presiding Officer issued an Initial Decision ordering each of the Respondents to pay civil money penalties of $579,000, comprised of $3,000 for each of the 193 violations of the MQSA for which each Respondent had been found liable.

On January 14, 2005, Respondents filed a Notice of Appeal and Request for Oral Argument. As set forth in this Brief in Opposition, none of the exceptions raised by Respondents on appeal is persuasive. Accordingly, both the Partial Summary Decision and the Initial Decision issued by the Presiding Officer should be affirmed.

ARGUMENT

I. STANDARD AND SCOPE OF REVIEW

On appeal from a presiding officer's initial decision or summary decision, the standard of review on a disputed issue of fact is whether the initial decision is supported by substantial evidence on the whole record. 21 C.F.R. § 17.47(k). The standard of review on a disputed issue of law is whether the initial decision is erroneous. Id.

The transcript of testimony, exhibits, and other evidence admitted at the oral hearing, and all papers and requests filed in the proceeding constitute the administrative record for review on appeal. 21 C.F.R. § 17.41(b). There is no right to appear personally

before the Departmental Appeals Board. 21 C.F.R. § 17.47(f). Respondents' request for oral argument should, therefore, be denied.

II. THE PLAIN LANGUAGE OF THE MQSA SUPPORTS THE PRESIDING OFFICER'S SUMMARY DECISION THAT RESPONDENTS ARE EACH LIABLE FOR 193 VIOLATIONS.

Respondents first challenge the Partial Summary Decision, claiming that because the Presiding Officer found each of them liable for one violation of 42 U.S.C. § 263b(h)(3)(A) (failure to obtain a certificate), he was precluded from finding each of them liable for 192 violations of § 263b(h)(3)(D) (one violation for each of the mammography examinations conducted by BIC while uncertified). Specifically, Respondents assert that their conduct in performing 192 mammography examinations while uncertified constitutes the "same act" as their failure to obtain certification. They claim that the penalty for such act is specifically covered by the express terms of 42 U.S.C. § 263b(h)(3)(A), which permits FDA to assess civil money penalties for a "failure to obtain a certificate." Respondents argue that the Presiding Officer's finding with respect to the additional 192 violations required him to read 42 U.S.C. § 263b(h)(3)(D), which allows FDA to assess civil money penalties for "each violation" of the MQSA, as creating multiple violations of the failure to obtain a certificate. Respondents contend that such a reading would render 42 U.S.C. § 263b(h)(3)(A) "completely superfluous" and is, therefore, impermissible.

Respondents' argument is flawed for two reasons. First, the plain language of the MQSA authorizes the Presiding Officer's finding. Second, Respondents' argument relies on the mistaken assumption that 42 U.S.C. § 263b(h)(3)(A) provides the exclusive means for holding them responsible for their conduct.

Under the most basic canon of statutory construction, the plain meaning of a statute controls unless it would lead to absurd results. E.g., Siddiqui v. United States, 359 F.3d 1200, 1202 (9th Cir. 2004); United States v. Jennings, 323 F.3d 263, 266-67 (4th Cir. 2003). In pertinent parts, 42 U.S.C. § 263b(h)(3) provides:

> [FDA] may assess civil money penalties in an amount not to exceed $10,000 for--
>
> (A) failure to obtain a certificate as required by [42 U.S.C. § 263b(b)] ... and
>
> * * *
>
> (D) each violation, or for each aiding and abetting in a violation of, any provision of, or regulation promulgated under, [42 U.S.C. § 263b] by an owner, operator, or any employee of a facility required to have a certificate. (Emphasis added).

As clearly reflected by the plain meaning of the foregoing language, FDA may assess a penalty for a "failure to obtain a certificate" and for each violation of any provision of the MQSA by an owner, operator, or any employee of a facility required to have a certificate.

As discussed in the Partial Summary Decision, Respondents are liable for penalties pursuant to both 42 U.S.C. § 263b(h)(3)(A) and 42 U.S.C. § 263b(h)(3)(D). Partial Summary Decision, at 8. Respondents failed to obtain a certificate, as required by 42 U.S.C. § 263b(b), for the period between and including May 7, 2002, and July 25, 2002, during which Respondents performed mammography. Id. By its terms, 42 U.S.C. § 263b(h)(3)(A) authorizes FDA to assess a civil money penalty against each Respondent for their "failure to obtain a certificate."

In addition, 42 U.S.C. § 263b(h)(3)(D) plainly states that FDA may assess a penalty for each violation, or for each aiding and abetting in a violation of, any provision of the MQSA by an owner, operator, or any employee of a facility required to have a

certificate. In this case, the repeated violation for which the Presiding Officer found Respondents liable is that of 42 U.S.C. 263b(b)(1), which states:

> No facility may conduct an examination or procedure ... involving mammography after October 1, 1994, unless the facility obtains –
>
> (A) a certificate –
> (i) that is issued, and if applicable, renewed, by the Secretary ...;
> (ii) that is applicable to the examination or procedure to be conducted; and
> (iii) that is displayed prominently in such facility; or
> (B) a provisional certificate –
> (i) that is issued by the Secretary ...;
> (ii) that is applicable to the examination or procedure to be conducted; and
> (iii) that is displayed prominently in such facility.

Id. (emphasis added).

According to its literal terms, 42 U.S.C. § 263b(b)(1) is violated each time that "an examination or procedure" is conducted while a facility lacks an effective certificate. Respondents conducted 192 mammography examinations while their facility lacked a valid certificate, in violation of 42 U.S.C. 263b(b)(1). Accordingly, as the Presiding Officer determined, Respondents are each liable, pursuant to § 263b(h)(3)(D), for 192 violations of 42 U.S.C. § 263b(b)(1). Based on its plain meaning, the MQSA authorizes the penalties imposed by the Presiding Officer.

This interpretation does not lead to absurd results. In fact, it is entirely consistent with the purpose of the MQSA. In enacting the MQSA, Congress noted that breast cancer was the most common cancer and the second leading cause of cancer deaths among women in the United States, and that the lifetime risk was increasing. H.R. Rep. No. 102-889, at 12 (1992). Congress also recognized that the best means of preventing death from advanced breast cancer is early detection, noting that mammography is

particularly valuable because it can detect breast cancer up to two years before a lump can be felt, greatly enhancing the patient's chance of survival. Id.

Despite the breast cancer risk, there were no national, comprehensive quality standards for mammography. Id. at 14. Rather, there was only a patchwork of federal, state, and private programs that were often voluntary or lacking important mammography quality evaluation criteria and oversight mechanisms. Id. As a result, there were great variations in mammography quality from facility to facility, leaving women with no guarantee that their mammograms were safe or accurate. Id. at 14-15. Congress also recognized that a mammogram is among the most difficult radiographic images to read and must have optimal clarity to be interpreted correctly. Id. Poor image quality or faulty interpretation can result in the failure to detect early lesions, delaying treatment and increasing the likelihood of death or mastectomy. Id.

To rectify this situation, the MQSA was enacted to establish uniform, national quality standards for mammography. See 58 Fed. Reg. 67565 (Dec. 21, 1993). The MQSA achieves this objective requiring a facility to obtain a certificate before it performs mammography examinations. A facility can only obtain such a certificate if it meets minimum mammography quality standards in the areas of equipment, personnel, and quality assurance.[1] Thus, the success of the MQSA in ensuring safe, high-quality mammography services depends, in large part, on compliance with the certification requirement.

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[1] To accomplish this goal, a facility must first be accredited by an FDA-designated accreditation body, which sets quality standards and evaluates a facility to determine if it meets those standards. Once FDA receives notice that a facility has been accredited, it can issue or renew a facility's mammography certificate. The accreditation body involved in this case was the American College of Radiology (ACR).

The plain meaning interpretation of the MQSA provides to FDA a reasonable enforcement mechanism to penalize violations of the statute's most fundamental requirement – that a facility obtain a certificate before performing any mammography examinations, to ensure that the films are as accurate and reliable as possible, given the critical nature of such films in diagnosing a serious disease. Under the plain meaning of the statute, FDA may assess penalties, pursuant to 42 U.S.C. § 263b(h)(3)(A), for failure to obtain a certificate during any period in which a facility performs uncertified mammography. It also permits FDA to assess penalties, pursuant to 42 U.S.C. § 263b(h)(3)(D), against a facility's owner, operator, and employee for each uncertified examination that the facility performs. This plain-meaning interpretation provides a strong deterrent to non-compliance with the certification requirement, affords FDA the discretion to enforce the objectives of the MQSA, and does not lead to absurd results.

By contrast, the interpretation urged by Respondents is inconsistent with the purpose of the statute and verges on absurdity. Under Respondents' proposed interpretation, FDA is only authorized to assess a civil money penalty for failure to obtain a certificate in an amount not to exceed $10,000 regardless of whether the facility performs one uncertified examination or 1,000 uncertified examinations. Clearly, Congress did not intend to limit the penalties for such egregious violations to a maximum amount of $10,000, as this result would not sufficiently deter a facility from failing to comply with the MQSA's core certification requirement.

Respondents also appear to rely on the canon of statutory construction that provides that a specific statutory provision prevails over a general provision. Respondents essentially argue that the specific reference to "failure to obtain a

certificate" in 42 U.S.C. § 263b(h)(3)(A) prevails over the general language in 42 U.S.C. § 263b(h)(3)(D), which authorizes penalties for any violation of the MQSA. Respondents' reliance on this rule is misplaced because there is no conflict between the two provisions that would preclude FDA from assessing penalties under both.

Specific statutory language controls over general language only when there is a conflict between the two. See e.g., National Cable & Telecommunications Assoc. v. Gulf Power Co., 534 U.S. 327, 335-37 (2002) (explaining that there is no conflict between two specific provisions of a telecommunications statute that are merely subsets of another more general provision, and thus the two specific provisions do not limit the general provision); see also Padberg v. McGrath-McKenchie, 108 F. Supp. 2d 177 (E.D.N.Y 2000) (holding that general rule penalizing a taxicab driver for "any willful act of omission or commission which is against the best interests of the public" did not conflict with the specific rule penalizing a driver's refusal of service to certain passengers).

In this case, the terms of 42 U.S.C. § 263b(h)(3)(D) do not conflict with 42 U.S.C. § 263b(h)(A). In fact, the two provisions can be construed together in such a manner as to give effect to both; the language of one does not preclude the application of the other. Under 42 U.S.C. § 263b(h)(3)(A), FDA may assess civil money penalties for failure to obtain a certificate during any period in which a facility performs uncertified mammography. This in no way contradicts 42 U.S.C. § 263b(h)(3)(D), which authorizes FDA to assess penalties for each violation, or each aiding and abetting in a violation, of any provision of the MQSA, including each mammography examination conducted without a certificate in violation of 42 U.S.C. § 263b(b)(1). In short, Respondents'

conduct falls within the scope of both 42 U.S.C. §§ 263b(h)(3)(A) and 263b(h)(3)(D), and Respondents can be held liable under both provisions.

III. CMP IS AN APPROPRIATE SANCTION UNDER THE MQSA.

Respondents next challenge the Initial Decision, arguing that because FDA (as delegated by the Secretary of Health and Human Services) allegedly failed to develop procedures with respect to when and how the CMP sanction is to be imposed, as required by 42 U.S.C. § 263(h)(4), the imposition of CMPs in this case was inappropriate in any amount. Hearing Transcript, at 44. Their premise is incorrect, however, and their argument must fail.

Title 42, United States Code, Section 263(h)(4) states that:

> [t]he Secretary shall develop and implement procedures with respect to when and how each of the sanctions is to be imposed under paragraphs (1) through (3). Such procedures shall provide for notice to the owner or operator of the facility and a reasonable opportunity for the owner or operator of the facility to respond to the proposed sanctions and appropriate procedures for appealing determinations relating to the imposition of sanctions.

In FDA's Compliance Program Guidance (CPG) Manual, the program addressing mammography facility inspections articulates procedures for the CMP sanction. CPG 7382.014, September 30, 1999, attached to Complainant's Post-Hearing Brief on Penalty Amount as Exhibit G-31, at Part III, Pages 11-15. The CPG makes clear that once-certified facilities whose certificates expires before they seek reaccreditation are among the type of facilities that "should be considered for regulatory action by the agency. Any facility can be assessed with civil money penalties or enjoined from operating if it is found to be operating while uncertified." Id. at 12. The CPG explains what is necessary to support a CMP action, and requires prior notice before considering that sanction:

> When evidence confirms that an uncertified facility is performing mammography, consideration should be given to the extent of the illegal operation and if there is evidence that the facility has quality problems. Evidence of quality problems might be that the facility was operating after being denied accreditation. Facilities that have performed mammography uncertified or continue to perform mammography uncertified may be subject to [CMPs] or an injunction.... Prior notice should be established before considering [CMPs]. Factors affecting severity could include the number of patients that were examined while uncertified, whether the facility knew that it was performing mammography uncertified (i.e., was it clear from correspondence that the facility received that they were no longer certified).... If documentation establishing illegal operation is adequate to support a case and prior notice has been established, the agency should consider a recommendation for CMPs.

Id. at 14-15.

The CPG also contains procedures for CDRH to pursue a Directed Plan of Correction (DPC) or Suspension under the MQSA, Id. at Part V, Page 4, and notes that "[s]imilar procedures will be used regarding the use of CMP. FDA has specific regulations for CMP procedures at 21 C.F.R. Part 17." Id. at Part V, Pages 3-4.

FDA's regulations in 21 C.F.R. Part 17 "set[ ] forth practices and procedures for hearings concerning the administrative imposition of civil money penalties by FDA." 21 C.F.R. § 17.1. The regulation specifies that CMPs under "Section 354(h)(2) of the [Public Health Service] Act, as amended by the [MQSA], authorizing civil money penalties for failure to obtain a certificate, failure to comply with established standards, among other things" are governed by the Part 17 procedures. 21 C.F.R. § 17.1(d).

The regulations in Part 17 are explicit, declaring what information must appear in a CMP complaint, explaining how the hearing will be conducted and how the amount of penalties and assessments are determined, and providing for both interlocutory and final appeals. See e.g., 21 C.F.R. §§ 17.5, 17.18, 17.34. These regulations and FDA's CPG regarding mammography inspections are the procedures required under 42 U.S.C.

§ 263(h)(4). Accordingly, Respondents' argument that the Secretary failed to devise procedures as required under the MQSA is incorrect, and CMP is an appropriate sanction under the MQSA.

In a related argument, Respondents claim that the government violated 42 U.S.C. § 263(h)(4) because it did not develop procedures to provide notice to the "owner or operator" of the facility. However, Respondents base their argument on the testimony of FDA witness Michael Divine, who testified about a different type of notice than that required by the statute. Respondents' argument is both legally and factually untenable.

First, although Respondents' cite Mr. Divine's testimony about notice of the impending expiration of the mammography certificate to Dr. Korangy, 42 U.S.C. § 263(h)(4) applies to a different type of notice. 42 U.S.C. § 263(h)(4) requires procedures concerning when and how the CMP sanction is to be imposed, including procedures for "provid[ing] notice to the facility owner or operator [and] a reasonable opportunity for the owner or operator to respond to the proposed sanction ...." Id. The plain language of the statute, therefore, makes it clear that the procedures that FDA was required to develop were with respect to the notice of the proposed CMP sanctions. Part 17 does exactly that by setting forth specific requirements for the content and service of the complaint for civil money penalties, which is the document that initiates the CMP action and notifies respondents of the proposed penalties, as well as the opportunity to contest them. See 21 C.F.R. §§ 17.5, 17.7. Clearly, CDRH's service of the complaint in this case comported with the requirements of 42 U.S.C. § 263(h)(4).

Second, in any event, CDRH has developed procedures for prior notice with respect to the impending expiration of mammography certificates. Michael Divine

testified that it is CDRH's procedure to send letters to facilities whose mammography certificates are about to expire. September 20, 2004 Hearing Transcript (Hearing Transcript), at 16. Such letters remind the facilities of the impending expiration date and notify the facility that performing mammography without a valid certificate is a violation of law that could subject the facility to sanctions. Id. at 16-17. Mr. Divine also testified that CDRH's procedure is to send such letters by "accountable mail," which he explained as overnight mail or delivery via a private contractor that provides confirmation to CDRH of the letters' delivery. Id. at 17-19.

Third, there is substantial evidence in the record to show that Respondents had actual notice of the expiration of their certificate before they conducted the 192 mammography examinations that serve as the basis for the civil money penalties here. Most notably, as the Presiding Officer recognized in the Partial Summary Decision, the May 6, 2002 expiration date of the mammography certificate was listed on the certificate itself, a fact that was never disputed by Respondents.[2] Partial Summary Decision, at 7, 9. The Presiding Officer reasoned, therefore, that Respondents knew or should have known that they were continually violating the MQSA by performing mammography

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[2] For a comprehensive discussion of the notice issue, see Complainant's Reply to Respondents' Opposition to Complainant's Motion for Partial Summary Judgment, filed May 21, 2004, at 2-11. In summary, however, the record reflects that Respondents were notified at least three times by letter that their certificate was about to expire. On April 1, 2002, CDRH sent a letter via first class mail address personally to Respondent Amile A. Korangy, M.D. at the address used by BIC on numerous documents. On April 29, 2002, ACR sent a letter to Respondents, which, among other things, stated, **"[Y]ou may not lawfully conduct mammography if your MQSA certificate expires."** Respondents acknowledged receipt and review of the April 29, 2002 letter. Finally, on May 1, 2002, CDRH sent another letter to Respondents. It is undisputed that the letter was sent via UPS Next Day Air Service, and was signed by a BIC employee named "Sonier."

examinations while uncertified. Id. For all of these reasons, Respondents' argument with respect to notice is unavailing.

IV. CDRH MET ITS BURDEN OF PROOF THAT THE CMP AMOUNT IS APPROPRIATE.

Next, Respondents argue that the Presiding Officer erred in his Initial Decision by rejecting Respondents' argument that CDRH did not establish the appropriate penalty amount by a preponderance of the evidence, as required by 21 C.F.R. § 17.33(b). Specifically, Respondents claim that CDRH did not consider supposedly mitigating factors, including Respondents' purchase of a new mammography machine and their supposed inability to pay a substantial penalty, including their alleged financial loss on each mammography performed. They also claim that the Presiding Officer should have found that CDRH was arbitrary and capricious in determining the amount of the penalties sought here as compared to the penalties sought in the civil money penalty complaint filed more recently In the matter of Ecumed Health Group, et al. Respondents' arguments again fail, and the Initial Decision should stand.

The "preponderance of evidence" standard of proof in a civil case is defined as "evidence which is of greater weight or more convincing than the evidence which is offered in opposition to it; that is, evidence which as a whole shows that the fact sought to be proved is more probable than not." Black's Law Dictionary, 6th ed. (1990), at 1182. The preponderance of the evidence shows that a significant CMP, such as the $3,000 per violation penalty sought by CDRH in its Post-Hearing Brief on Penalty Amount, is appropriate in this case.

Throughout the proceedings, Respondents never disputed the facts underlying the Presiding Officer's finding that they are each liable for 193 violations of the MQSA—

that BIC conducted 192 mammography examinations while uncertified between May 7, 2002 and July 25, 2002. Respondents' conduct, committed over a period of two months, put almost 200 patients at risk that their mammograms would not detect breast cancer at a stage where treatment would be most effective. In addition, CDRH presented ample evidence that Respondents committed these offenses with notice that their certificate had expired and that they could not lawfully conduct mammograms without a valid certificate. See Section III., supra, at 12-13 and n.2. CDRH also considered the facility's history, including the fact that it had received a prior Warning Letter for quality control violations, and the fact that other MQSA violations were found at the time that it was operating while uncertified. See Hearing Transcript, at 21. This evidence, along with Congress' finding that each violation of the MQSA warrants a penalty up to $10,000, see Section II., supra, supports the penalty sought by CDRH and awarded by the Presiding Officer.

A. Respondents' Failed To Prove Mitigating Factors By A Preponderance Of The Evidence.

The record soundly refutes Respondents' claims with respect to the mitigating factors alleged on appeal. Initially, it is notable that Respondents neglect to mention that the burden of proving any affirmative defenses or mitigating factors by a preponderance of the evidence is on them, rather than on CDRH. See 21 C.F.R. § 17.33(c). This is a burden that Respondents failed to meet.

1. Respondents' belated installation of a new mammography machine does not entitle them to a penalty reduction.

Respondents claim that they are entitled to a reduction in penalty because they supposedly ordered a new mammography machine before they were informed that their

existing machine would not warrant recertification. Respondents first raised this claim on June 2, 2004, when they submitted the Direct Testimony of Amile A. Korangy. Exhibit R-1 attached to that testimony appears to be a quotation for new equipment but does not state when the equipment was actually ordered. While the date of the order is not relevant to the penalty issue, it is notable that the new equipment was not installed until at least June 28, 2002, and Respondents conducted 165 of the 192 uncertified examinations at issue on the old equipment. See Divine Decl., Ex. G-D to Complainant's Motion, ¶ 21 and Ex G-10 thereto; see also Hearing Transcript, at 24 ("I believe that the machine in question was purchased—or was actually started to be used somewhat later after the facility had already had their certificate expire.") Accordingly, Respondents' purchase of new equipment should have been afforded little weight as a mitigating factor.

2. Respondents have failed to prove their inability to pay.

Respondents have also failed to prove by a preponderance of the evidence their claimed inability to pay the civil money penalties imposed. When CDRH initiated this action, it sought the maximum amount of CMP provided for by statute because of Respondents' blatant failure to comply with MQSA after receiving several notices regarding its certification status and because of the nearly 200 women that Respondents put at risk of misdiagnosis by conducting mammography while uncertified. See Administrative Complaint for Civil Money Penalty, ¶¶ 10-13, 21-23. The statute provides for a maximum penalty of $10,000 per violation, per Respondent, 42 U.S.C. § 263b(h)(3), which in this case led to a Complaint seeking a total of $3.86 million.

At the time that the Complaint was filed, CDRH had no specific financial documents regarding Respondents' financial situation. See Hearing Transcript, at 26-27.

Contrary to Respondents' allegations, CDRH remained willing throughout the proceedings to consider Respondents' inability to pay. Id. at 28-29 (stating that credible documentation of inability to pay, if received, would be considered by CDRH in reducing the amount of the penalty). Respondents, however, were less than forthcoming with their financial information. The financial documents eventually provided by Respondents, coupled with the information obtained by CDRH independently, suggested that Respondents have substantially more assets than they ever admitted.

Throughout the proceeding, Respondents objected to CDRH's discovery attempts to obtain financial information. Specifically, in its First Request for Production of Documents served on January 13, 2004, CDRH requested "[a]ll documents reflecting any or all of the assets, including any ownership interests in any business entity, of each of the Respondents and any of Dr. Amile Korangy's immediate family members," (Request 2) and broadly asked for all documents relating to the annual receipts of Respondents and their affiliates (Request 4).

On January 26, 2004, Respondents filed a Request for Protective Order regarding these discovery requests. On January 30, 2004, the parties filed a Joint Notice and Agreement to Resolve Discovery Dispute (Joint Notice) in which Respondents agreed to respond to certain of CDRH's document requests for financial information no later than sixty days prior to (1) filing any motion, proposed findings of fact, evidence, or any other written document in this proceeding in which all or either of them claim entitlement to a reduction of civil money penalties based on their inability to pay; or (2) the hearing in this proceeding if all or either of them claim, or offer evidence in support of a claim, during such hearing, that they are entitled to a reduction of civil money penalties based

on their inability to pay. Joint Notice, at 2-5. The Joint Notice further provided that if Respondents failed to respond to CDRH's financial document requests sixty days prior to filing such document, or the hearing, as described above, Respondents agreed that the Presiding Officer should exclude any evidence of their inability to pay or entitlement to reduction of civil money penalties that is submitted in support of such written document and/or hearing. Id. On April 7, 2004, the Presiding Officer denied both of Respondents' Requests for Protective Order regarding CDRH's Request for Production of Documents Numbers 2 and 4, ruling that "Respondents' financial data would be relevant to any determination [of penalty amount] under 21 C.F.R. § 17.34. April 7, 2004 Order, ¶¶ 2-3.

Notwithstanding the Presiding Officer's Order regarding the discovery request and Respondents' invocation of the inability to pay defense in various pleadings and at the September 20, 2004 hearing, Respondents never fully responded to CDRH's second and fourth requests for financial information in Complainant's First Request for Production of Documents. Instead, Respondents provided CDRH with incomplete tax returns and, only after significant delay and much prodding from CDRH, only some small number of the specific documents CDRH requested by letters dated October 1, 2004 and November 8, 2004, and orally on approximately November 22, 2004. See Exhibit G-14 attached to Complainant's Post-Hearing Brief.[3]

In any event, Respondents were not entitled to a penalty reduction due to their unsupported claim of inability to pay. It was Respondents' burden to prove inability to pay, and they did not do so. It is worth noting that the only financial document that Respondents even mention on appeal is their self-created "2003 Mammography

[3] Exhibits G-14 through G-31 cited infra were admitted into the record as attachments to Complainant's Post-Hearing Brief.

Profit/Loss Statement," attached as Exhibit R-4 to Direct Testimony of Amile A. Korangy, which purports to show that their expenses for each mammography were more than the amount of reimbursement per procedure. The statement, which is not supported by any documentation and does not reflect the overall profit and loss of the corporation or the overall financial condition of either of the Respondents, is a prime example of the type of incomplete and self-serving "financial documents" provided by Respondents. Another example is the statement of assets and liabilities that Respondents reluctantly provided a few days before the oral hearing, but which was not audited. See Hearing Transcript, at 39-40. In fact, the documents eventually provided post-hearing in response to CDRH's repeated requests, as well as the information that CDRH was able to discover from public tax and real property records, suggest that Respondents have access to substantially more assets than they revealed to CDRH or the Presiding Officer.

For example, Amile Korangy maintained throughout this proceeding that he owns no real property in his name. See e.g., Hearing Transcript, at 39. While that appears to be technically true, documents obtained by CDRH paint a picture of a man who, since at least 1996, has taken great measures to avoid holding any property in his own name by transferring it to his wife and children, into trusts, or into the name of a company that is not readily traceable to him.

Dr. Korangy's activities regarding the ownership of his residence at 13607 Sheepshead Court, Clarksville, MD, 21029, a 7,786 square foot house on 3.38 acres of land (see Exhibit G-15), demonstrate this point. On December 23, 2003, after a series of

transfers of this property beginning in 1996[4] and two months after this action was filed, Dr. Korangy transferred this home out of his name into a trust for which his wife, Parvane S. Korangy, is trustee. See Exhibit G-16, at 5. Although Dr. Korangy claimed that he does not own this residence, it is quite clear from the pattern of transfers that he has full control over the home. Moreover, given that his wife's W-2 Wage and Tax Statement from 2003 records her wages, tips, or other compensation as just over $[redacted] the available evidence strongly suggests that Dr. Korangy, not his wife, is responsible for the payments and maintenance costs of this home. See Exhibit G-17. As of January 1, 2002, this property was valued for tax purposes at $987,580. See Exhibit G-15. The market value of this home is most likely significantly more than the tax assessment value, based on the limited evidence that the government could gather through public records regarding comparable homes under contract, probably in the $1.2 to $1.5 million range.

Dr. Korangy's pattern of ensuring that his assets are held in another name is also reflected in his car registration. At the oral hearing, Dr. Korangy stated that he does not have a car and that he did not have a car in his name. Hearing Transcript, at 40-41. When CDRH requested titles to vehicles or other documents reflecting ownership of vehicles by Respondents, Respondents first gave CDRH Purchase Orders and Bills of Sale for a used 2000 Toyota Corolla registered in the name of BIC and a used 1998

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[4] Since 1996, there have been several curious transfers of ownership for this property. See Ex. G-16. On March 22, 1996, the property transferred from Amile A. Korangy to The Korangy Family Revocable Trust. On December 9, 1998, the property transferred from The Korangy Family Revocable Trust to Amile A. and Parvane S. Korangy, tenants by the entirety. That same day, Amile A. Korangy transferred the property to a trust with himself as the trustee. Then, on December 23, 2003, as trustee, Amile A. Korangy transferred the property back to himself and Parvane S. Korangy as tenants by the entirety, and then transferred the property to a trust with Parvane S. Korangy as trustee. The two transfers on December 23, 2003 occurred two months after the filing of this action and removed Amile Korangy's name from the property entirely.

documents regarding his assets in Paskor, and his involvement in Paskor is further evidence that he has additional undisclosed assets from which he is able to pay a CMP.[5]

Dr. Korangy's 2003 personal tax return shows dividends in the amount of [redacted] from Legg Mason Wood Walker, Inc. See Exhibit G-25. When CDRH questioned Dr. Korangy about the underlying investment giving rise to these dividends, Dr. Korangy, consistent with his pattern of denying ownership of assets, answered that "the [redacted] dividend by Legg Mason belongs to my wife's account and does not belong to me." See Letter to Mr. Schwartz from Amile A. Korangy, Exhibit G-26. Again, Dr. Korangy failed to provide CDRH with any documentation of this investment.

Dr. Korangy and KRA own condominiums at 724 Maiden Choice Lane, Baltimore, MD, 21228, Units C1B, C1C, and C1D, which were assessed for tax purposes as of January 1, 2003, at $114,500, $209,100, and $137,900, respectively. See Exhibit G-27. Through his company Pikesville Properties, LLC, Dr. Korangy also owns property at 6609 Reisterstown Road, Baltimore, MD, 21215, that he bought for $1,000,000 on January 22, 2002. See Exhibit G-28. And on July 30, 2004, Dr. Korangy registered another radiology facility in Frederick, Maryland, called Frederick Imaging Center, LLC. See Exhibit G-29. In total, Dr. Korangy operates at least six radiology facilities, three of which perform mammography examinations. Hearing Transcript, at 38.

KRA's 2003 tax return, which shows a net loss of approximately $[redacted] states that the company began tax year 2003 with buildings and other depreciable assets worth $[redacted] and ended that tax year with buildings and other depreciable assets worth

[5] When questioned about Paskor on November 29, 2004, Dr. Korangy relayed through counsel that he sold the property in Indian River County, FL, in 1999 to a group, including two of his children. He stated that he received some money from the sale, which he put into his business, but that he had no ownership in Paskor.

$[redacted]. See 2003 1120S for KRA, Exhibit G-30. Thus, KRA purchased or acquired another $1.2 million worth of buildings and other appreciable assets in the 2003 tax year, yet Respondents never provided CDRH with any information about those assets, all the while contending that they did not have the ability to pay the CMP.

Thus, it is quite clear that Dr. Korangy has engaged in creative asset management. Based on the limited number of records provided to CDRH or available publicly, he and KRA likely own real estate worth over $4 million, including Dr. Korangy's residence and KRA's properties. Although the tax returns provided by Respondents would seem to suggest that Dr. Korangy and his wife make only $[redacted] see Exhibit G-25, and that KRA is operating at a loss, see Exhibit G-30, it is quite clear that Respondents have numerous assets available to them to pay a significant CMP in this case. Indeed, Respondents' activities in hiding assets from CDRH constituted an aggravating factor that the Presiding Officer properly considered under 21 C.F.R. § 17.34(a) when determining an appropriate CMP in this matter. See Initial Decision, at 8.

However, despite Respondents' financial manipulations, CDRH voluntarily reduced the amount of penalty to less than one third of the penalty that it originally sought, recognizing that a CMP is a remedial fine rather than a punishment and that this sum would induce future compliance. Because CDRH believed that Dr. Korangy personally has substantially more assets than he admitted and that the corporate Respondent owns property worth over $3,000,000, and given Respondents' obstinate refusal to supply any meaningful documents to support their claim of inability to pay, it requested that the Presiding Officer impose a total penalty amount of $1,158,000 ($579,000 for each Respondent), based on a $3,000 penalty for each of the MSQA

Volkswagen Jetta GLX registered in the name of KRA. See Exhibit G-19. Only after Complainant asked for final confirmation that the Corolla and Jetta were the only vehicles owned by KRA and/or Amile Korangy did Respondents produce evidence of the purchase of two additional, and far more expensive cars: a 2003 Mercedes Benz E500 purchased for $72,525.60 on April 28, 2003, in the name of BIC and a GMC Yukon XL purchased for $49,085.20 on June 21, 2003, in the name of "Baltimore Imagine (sic) Center, Michael Shahram Korangy." See Exhibit G-20. Thus, in 2003 alone, Dr. Korangy purchased two cars worth over $120,000, but neither is registered in his name.

Additionally, on December 1, 1999 and January 24, 2000, Dr. Korangy transferred real property that he owns in Indian River County, Florida, out of his name into a company called Paskor, LLC (Paskor). See Exhibit G-21. This company was registered with the Florida Department of State on December 6, 1999, and the registered mailing address for the company is 13607 Sheeps Head Court, Clarksville, MD 21029, which is Dr. Korangy's residence. See Exhibit G-22. In the Florida filing, Dr. Korangy is a listed as the MGRM (Managing Member) of Paskor. Id. The property owned by Paskor, which consists of multiple lots along Highway AIA in Vero Beach, was assessed in 2004 at $249,260. See Exhibit G-21; Exhibit G-23. On November 1, 2004, the TCPalm website reported that "Paskor LLC of Clarksville, Md., wants to develop 3.7 acres of oak-covered woodland west of State Road A1A and south of Seaview Drive" in Indian River County. See Exhibit G-24. Dr. Korangy never provided CDRH with any

documents regarding his assets in Paskor, and his involvement in Paskor is further evidence that he has additional undisclosed assets from which he is able to pay a CMP.[5]

Dr. Korangy's 2003 personal tax return shows dividends in the amount of $5,473, from Legg Mason Wood Walker, Inc. See Exhibit G-25. When CDRH questioned Dr. Korangy about the underlying investment giving rise to these dividends, Dr. Korangy, consistent with his pattern of denying ownership of assets, answered that "the $5,000 dividend by Legg Mason belongs to my wife's account and does not belong to me." See Letter to Mr. Schwartz from Amile A. Korangy, Exhibit G-26. Again, Dr. Korangy failed to provide CDRH with any documentation of this investment.

Dr. Korangy and KRA own condominiums at 724 Maiden Choice Lane, Baltimore, MD, 21228, Units C1B, C1C, and C1D, which were assessed for tax purposes as of January 1, 2003, at $114,500, $209,100, and $137,900, respectively. See Exhibit G-27. Through his company Pikesville Properties, LLC, Dr. Korangy also owns property at 6609 Reisterstown Road, Baltimore, MD, 21215, that he bought for $1,000,000 on January 22, 2002. See Exhibit G-28. And on July 30, 2004, Dr. Korangy registered another radiology facility in Frederick, Maryland, called Frederick Imaging Center, LLC. See Exhibit G-29. In total, Dr. Korangy operates at least six radiology facilities, three of which perform mammography examinations. Hearing Transcript, at 38.

KRA's 2003 tax return, which shows a net loss of approximately $380,000, states that the company began tax year 2003 with buildings and other depreciable assets worth $1,294,646 and ended that tax year with buildings and other depreciable assets worth

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[5] When questioned about Paskor on November 29, 2004, Dr. Korangy relayed through counsel that he sold the property in Indian River County, FL, in 1999 to a group, including two of his children. He stated that he received some money from the sale, which he put into his business, but that he had no ownership in Paskor.

$2,585,707. See 2003 1120S for KRA, Exhibit G-30. Thus, KRA purchased or acquired another $1.2 million worth of buildings and other appreciable assets in the 2003 tax year, yet Respondents never provided CDRH with any information about those assets, all the while contending that they did not have the ability to pay the CMP.

Thus, it is quite clear that Dr. Korangy has engaged in creative asset management. Based on the limited number of records provided to CDRH or available publicly, he and KRA likely own real estate worth over $4 million, including Dr. Korangy's residence and KRA's properties. Although the tax returns provided by Respondents would seem to suggest that Dr. Korangy and his wife make only $132,593, see Exhibit G-25, and that KRA is operating at a loss, see Exhibit G-30, it is quite clear that Respondents have numerous assets available to them to pay a significant CMP in this case. Indeed, Respondents' activities in hiding assets from CDRH constituted an aggravating factor that the Presiding Officer properly considered under 21 C.F.R. § 17.34(a) when determining an appropriate CMP in this matter. See Initial Decision, at 8.

However, despite Respondents' financial manipulations, CDRH voluntarily reduced the amount of penalty to less than one third of the penalty that it originally sought, recognizing that a CMP is a remedial fine rather than a punishment and that this sum would induce future compliance. Because CDRH believed that Dr. Korangy personally has substantially more assets than he admitted and that the corporate Respondent owns property worth over $3,000,000, and given Respondents' obstinate refusal to supply any meaningful documents to support their claim of inability to pay, it requested that the Presiding Officer impose a total penalty amount of $1,158,000 ($579,000 for each Respondent), based on a $3,000 penalty for each of the MSQA

violations for which each Respondent is liable. The Presiding Officer's decision to impose the reduced penalty sought by CDRH is supported by substantial evidence in the record, as set forth above, and should be upheld.[6]

3. CDRH's determination of the penalty amount was not arbitrary and capricious.

Respondents' claim that CDRH's penalty determination was arbitrary and capricious because it differed from the initial penalty sought another case (In the matter of Ecumed Health Group, et al.) must also fail. When reviewing a claim that an agency action was arbitrary and capricious, the reviewing body is not permitted to substitute its judgment for that of the agency. Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co., 463 U.S. 29, 43 (1983) (quotation omitted). If the agency examined the relevant data and articulated a satisfactory explanation for its action, including a "rational connection between the facts found and the choice made," then the action must be upheld. Id. "This standard of review gives agency decisions a high degree of deference." Sierra Club v. United States Environmental Protection Agency, 252 F.3d 943, 947 (8th Cir. 2001) (internal quotations omitted).

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[6] Apparently not satisfied with the substantial reduction in penalty, Respondents argue that the Presiding Officer had no power to revise the proposed sanction, given CDRH's alleged failure to meet the burden of proof requirement in 21 C.F.R. § 17.33 and to establish procedures pursuant to 42 U.S.C. § 263b(h)(4). See Respondents' Notice of Appeal and Memorandum, both at Section B.3. This repeats the arguments set forth in Sections B.1 and 2 of Respondents' Notice of Appeal and Memorandum, which are addressed above. Respondents also claim that the Presiding Officer had no rationale to justify the modified CMP other than to state that CDRH has expressed a willingness to modify the penalty. Respondents' Memorandum, at Section B.3. The Presiding Officer was fully empowered by 21 C.F.R. § 17.34 to evaluate any mitigating or aggravating circumstances, and did so in this case. Furthermore, the Partial Summary Decision and Initial Decision set forth an adequate basis for the decision here.

In this case, the record reveals that both CDRH and, subsequently, the Presiding Officer carefully examined the relevant factors and reached a decision with respect to the penalty amount that was rationally connected to the facts found. CDRH's initial decision to ask for the maximum penalty amount of $10,000 per violation per Respondent was supported numerous facts including, but not limited to: Respondents' knowing and willful violations of the MQSA; the length of time (over two months) that Respondents remained uncertified; the number of mammography examinations (192) performed during that time; that 165 of those mammography examinations were performed on a machine that Respondents' were told would not allow them to be recertified; the Respondents' history, including a prior FDA Warning Letter for quality control violations; additional violations found at the time that FDA discovered that Respondents were conducting mammography while uncertified; the extent of Dr. Korangy's personal involvement in the uncertified mammography; the extent of Respondents' experience with the MQSA, including the number of other mammography facilities operated by Respondents; and the lack of any documentary evidence indicating that Respondents would not have been able to pay the total penalty of $3.86 million sought.

Later in the proceedings, CDRH had opportunity to evaluate supposed mitigating factors alleged by Respondents in their Proposed Findings of Fact, but as set forth in Complainant's Opposition to those Proposed Findings of Fact, filed August 27, 2004, those factors were largely contradicted by the record. Eventually, despite Respondents' obstinate refusal to provide any meaningful documents supporting their claim of inability to pay, CDRH was able to obtain some documents from Respondents and from its own investigation of public records. As set forth in detail above, those documents show that

Respondents appear to have substantially more assets than they admitted. Based on this record, CDRH was justified in its initial decision to ask for the maximum penalty against Respondents and would have been justified in continuing to seek that amount in its Post-Hearing Brief. Nevertheless, CDRH considered the remedial nature of the penalty and Respondents' claims, albeit unsupported, that the maximum penalty would bankrupt them and reduced the penalty sought to less than one third of the original amount, for a total penalty of $1.158 million, or $3,000 per violation per Respondent. As the record reflects, therefore, CDRH carefully considered all of the relevant factors, which it subsequently presented to the Presiding Officer, before reaching its determination. Accordingly, neither CDRH's, nor the Presiding Officer's, decision can be considered to be arbitrary and capricious.

The Complaint filed in Ecumed does not change that analysis. Respondents' make much of the fact that the Complaint in Ecumed seeks $10,000 per violation against each respondent for failure to obtain a mammography certificate, but only $1,000 per violation for each mammography examination performed without a certificate. However, as the Presiding Officer recognized in his Initial Decision, "[s]ince a determination of CMPs necessarily involves consideration of only those factors present in each individual proceeding, Respondents' comparison is totally irrelevant. Even if there were some basis for making such a comparison, it is totally inappropriate here because the [Ecumed] matter referred to (FDA Docket No. 2004H-1322) is an ongoing proceeding in its early stages pending discovery and the introduction of evidence." Initial Decision, at 4.

The Presiding Officer's observation is correct. Contrary to Respondents' assertions, all relevant factors, such as those considered by CDRH in this case, are not

contained in the Ecumed complaint. For example, there is no mention of the qualifications of Respondents, their level of involvement in the alleged violations, or their prior violations or experience with the MQSA. In addition, had CDRH asked for a $10,000 penalty per violation per Respondent in the Ecumed case, the total penalty sought in the complaint would have been over $43 million, well over ten times the penalty initially sought here and nearly 40 times the final penalty amount sought. CDRH has an obligation to look at the total amount of penalty, in light of its remedial purpose, in addition to the penalty amount per violation when fashioning an appropriate penalty in a particular case. For this reason, too, Respondents' arbitrary and capricious argument is unavailing.

V. THE PRESIDING OFFICER DID NOT VIOLATE RESPONDENTS' DUE PROCESS RIGHTS.

Finally, Respondents claim that the Presiding Officer violated their due process rights by admitting into evidence documents attached by Complainant to its Post-Hearing Brief on Penalty Amount over Respondents' motion to strike and without providing Respondents an opportunity to respond. Specifically, Respondents moved to strike two categories of exhibits that CDRH attached to its Post-Hearing Brief on Penalty Amount: (1) Exhibit G-31, which was the FDA Compliance Program Guide (CPG) 7382.014 regarding mammography facility inspections; and (2) Exhibits G-15 to G-25 and G-27 to G-29, which were documents relating to Respondents' assets and ability to pay, some of which were obtained by CDRH from the public record and some of which were provided by Respondents themselves. All of these documents were relevant to rebut the purported mitigating factors set forth by Respondents with respect to the penalty amount.

Accordingly, the decision to admit them into evidence was well within the Presiding Officer's discretion, pursuant to 21 C.F.R. § 17.39(g), and should be upheld.

Respondents claim that Exhibit G-31, the mammography facility inspection CPG, should have been stricken from the record because it was not presented by CDRH prior to the oral hearing in this case, "as required," nor was it presented at the hearing where Respondents could have reviewed it and perhaps cross-examined CDRH's witness about it. Contrary to Respondents' argument, CDRH was not "required" to introduce the CPG before or during the hearing. Respondents did not ask for the CPG in discovery, although they certainly could have. Nor did CDRH seek to introduce the document as part of its case-in-chief. Therefore, CDRH had no obligation to introduce it into the record or to provide it to Respondents in advance of the hearing as required by 21 C.F.R. § 17.35 and this Presiding Officer's November 13, 2003 scheduling Order.

In fact, it was not until the conclusion of that hearing--at which the parties were expected to cross-examine witnesses about the proper penalty amount based on written evidence and testimony previously exchanged by the parties--that Respondents, for the first time, informed CDRH that they would argue, in their post-hearing brief, that no penalty should be imposed because FDA supposedly did not develop procedures as required by the MQSA. See Hearing Transcript, at 44. Under those circumstances, CDRH could not have been expected to anticipate such an argument or to have the CPG available at the hearing. However, because Respondents belatedly introduced the issue of procedures, the Presiding Officer properly used his discretion as permitted by 21 C.F.R. §

17.39(g) to allow CDRH to introduce the CPG as evidence to rebut Respondents' argument.[7]

Respondents' due process claim based on their motion to strike Exhibits G-15 through G-25 and G-27 through G-29, which were introduced by CDRH to counter Respondents' claim of inability to pay, is nothing short of ironic, given Respondents' repeated refusal to produce financial information to support that claim. Respondents allege that these documents should have been stricken because they were not presented pre-hearing or at the hearing and, therefore, Respondents could not respond or cross-examine any witnesses about the documents.

However, as CDRH has set forth both at the hearing, in its Post-Hearing Brief, and in its Opposition to Respondents' Motion to Strike, Respondents should not even have been permitted to argue inability to pay or to present any evidence thereof at the hearing due to their breach of the Joint Notice and Agreement to Resolve Discovery Dispute (Joint Notice) filed by the parties on January 30, 2004. See Hearing Transcript, at 5-6; Section IV.A.2, supra, at 16-17. Because Respondents' failed to respond to

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[7] Respondents claim that the CPG was presented to rebut CDRH's own witness, Michael P. Divine. However, although Respondents' counsel questioned Mr. Divine about procedures, he did not pose his questions in a manner that would have elicited testimony about the CPG. When asked about FDA procedures with respect to assessing CMPs, Mr. Divine set forth a detailed process of evaluation of a proposed CMP action by several components of FDA. See Hearing Transcript, at 11-12. Respondents' counsel characterized that process as "an internal procedural process" and then asked Mr. Divine if there were "any substantive guidelines that the FDA follows with respect to the issuance of civil money penalties." Id. at 12-13. Mr. Divine then responded that there was no formal guidance specifically with respect to CMP cases, but that there was a draft guidance. Id. at 13. It is evident from his answer that Mr. Divine interpreted counsel's question as referring to a document relating solely to CMP cases and not to the broader CPG addressing mammography facility inspections and the variety of sanctions that can result from a violation. In any event, it is clear that the CPG and 21 C.F.R. Part 17 satisfy the requirement that the Secretary develop and implement procedures with respect to when and how each of those sanctions is to be imposed. See Section III, supra.

CDRH's discovery request for financial documents no later than 60 days before the oral hearing, they should have honored the agreement set forth in the Joint Notice that Presiding Officer exclude evidence and argument related to their purported inability to pay. Not only did they ignore that agreement and repeatedly argue inability to pay based on a small number of hand-picked financial documents, they sought to prevent CDRH from rebutting such argument and providing the Presiding Officer with a more complete picture of their financial situation.

Despite Respondents' breach of the Joint Notice, the Presiding Officer indicated at the oral hearing that he was inclined to consider all of the documents available, including those relevant to inability to pay, in his determination of the penalty amount. See Hearing Transcript, at 7. Accordingly, CDRH's counsel requested an opportunity to submit rebuttal documents as an alternative to arguing that evidence and argument regarding inability to pay should not be considered. Id. at 5-6. Given that it was Respondents' burden to prove a claimed mitigating circumstance such as inability to pay, 21 C.F.R. § 17.33(c), CDRH should at least have had an opportunity to present evidence to counter such a claim. In light of the circumstances, therefore, the Presiding Officer's decision to admit CDRH's rebuttal evidence on the issue of ability to pay into the record was also a proper exercise of discretion and not a violation of due process.

Respondents' assertions regarding the Presiding Officer's refusal to afford them an opportunity to respond to CDRH's rebuttal evidence also fall far short of establishing a due process violation. While Respondents claim on one hand that there was no opportunity to address the issues related to the financial documents, they appear to base this lack-of-opportunity argument on the Presiding Officer's decision to reject their Reply

to Post-Hearing Brief of Complaint. That Reply is a two-page document that says nothing at all about the financial documents, but merely reiterates Respondents' legal arguments in summary fashion. Even now, Respondents never even allege that they do not own the assets set forth in the documents attached to Complainant's Post-Hearing Brief.

Moreover, Respondents were afforded adequate due process throughout the proceedings--more than adequate, given that they were allowed to argue inability to pay despite their breach of the Joint Notice. The decision to argue inability to pay was always theirs, and they were, at all times, in the best position to argue their financial position. They could have participated fully in the discovery process. And upon complete discovery, they could have fully briefed the issue of inability to pay months ago. They chose not to, opting instead to engage in gamesmanship with CDRH over their financial documents. Accordingly, the Presiding Officer's decision to reject belated arguments from Respondents' without good cause for the delay was not a violation of Respondents' due process rights.

CONCLUSION

For the foregoing reasons, the Departmental Appeals Board should affirm the Partial Summary Decision and Initial Decision of the Presiding Officer.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on this 23rd day of February, 2005, I have caused a copy of the foregoing Complainant's Brief in Opposition to Respondents' Appeal and Request for Oral Argument to be served by Federal Express overnight delivery, on:

Henry E. Schwartz
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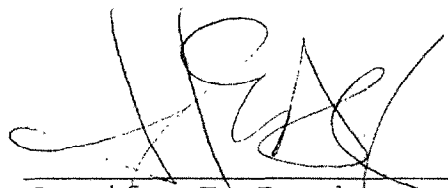

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